

## REMARKS

### Administrative Overview

The Office action dated March 23, 2006, examined claims 47-70. The Office action rejected claims 47-57, 60-61, 64-66, and 68-70 under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2003/0232445 (**Fulghum**). The Office action rejected claims 58-59, 62-63, and 67 under 35 U.S.C. 103(a) as allegedly being unpatentable over **Fulghum**.

Without acquiescing to any of the rejections, Applicants amend independent claims 47, 56, 68, and 69, and Applicants add new dependent claims 71-82 as reflected in the Listing of Claims above. Applicants also amend dependent claims 65 and 66 for form. Support for the amendments and new claims appears in the specification as originally-filed, for example, as indicated in the chart below. No new matter is added.

<u>Claim number(s)</u>	<u>Examples of support for amended claim/new claim in application as originally-filed</u>
47, 56, 68, 69	Page 26, line 18, to page 28, line 6
71, 74, 77, 80	Page 26, lines 18-20
72, 75, 78, 81	Page 27, line 21, to page 28, line 2
73, 76, 79, 82	Page 20, line 9

Following entry of this paper, claims 47-82 will be pending.

### **Fulghum** is not prior art under 35 USC 102(e)

**Fulghum** was filed on January 17, 2003, while the present application is a straight continuation of U.S. Patent Application No. 10/243,535, which was filed on September 13, 2002, predating **Fulghum**. Therefore, **Fulghum** is not prior art with respect to the present application under 35 USC 102(e).

Without acquiescing to any rejection of the Office action and without acquiescing to any allegation that **Fulghum** is prior art with respect to the present application, Applicants present arguments below which explain how the pending claims of the present application are patentably distinguished from **Fulghum**, in the event rejections similar to those of the Office action are contemplated in light of U.S. Provisional Patent Application No. 60/349,958, to which **Fulghum** claims priority.

Furthermore, Applicants reserve the right to file an affidavit or declaration under 37 CFR 1.131 to establish invention of the subject matter of any or all claims of the present application prior to the filing date of the **Fulghum** provisional.

Each of independent claims 47, 56, 68, and 69, and, thus, all of their dependent claims, are patentably distinguished from Fulghum

Without acquiescing to any rejection, Applicants amend each of independent **claims 47, 56, 68, and 69** to recite the following:

illuminating optics for illuminating a region of a tissue sample with electromagnetic radiation incident at a first angle and subsequently for illuminating the region of the tissue sample with electromagnetic radiation incident at a second angle

The amendments are supported in the specification as originally filed, for example, at page 26, line 18, to page 28, line 6. Each of **claims 47, 56, 68, and 69** also recite the following [emphasis added]:

a first set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the first angle

a second set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the second angle

**Fulghum** does not disclose illuminating a region of a tissue with electromagnetic radiation incident at a first angle, and then illuminating the region with electromagnetic radiation incident at a second angle. Reproduced below is Figure 8 of **Fulghum**, cited in the Office action:

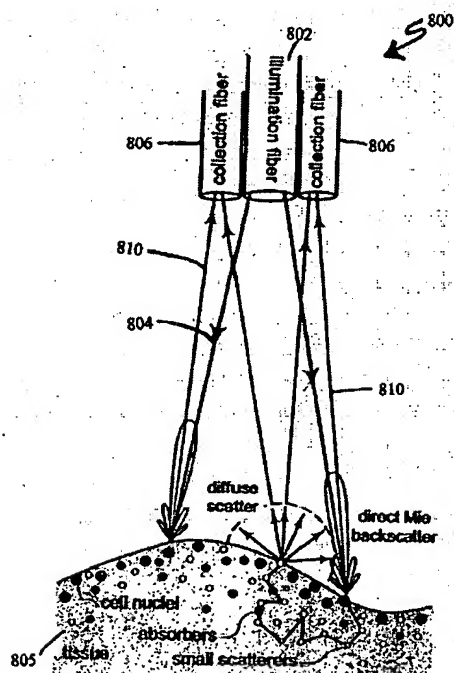


Figure 8 of **Fulghum** shows two different collection locations (806), but only one illumination source (802). Light is collected simultaneously at the two collection fibers (806). **Fulghum** does not illuminate a region at a first angle and subsequently illuminate the region at a second angle to obtain two sets of spectral data, as recited in each of the independent claims of the present application.

Furthermore, it would not be obvious to modify **Fulghum** to practice the subject matter of any claim of the present application, because the apparatus of **Fulghum** performs a different method for a different purpose. For example, **Fulghum** does not describe an apparatus for identifying spectral artifacts by illuminating tissue with light incident at two different angles; instead, **Fulghum** describes an apparatus for determining particle size distribution by analyzing Mie scattering from light obtained at two different locations.

**Fulghum** explains the apparatus of Figure 8 in paragraph [0092], page 8, a portion of which is reproduced below:

The tip of a typical probe 800 is shown schematically in a simplified form in FIG. 8. A central, illumination optical fiber 802 delivers "white light" 804 to the tissue 805 and separate collection optical fibers 806 return backscattered light 810 into a relatively narrow range of angles. The amount of light collected by these optical fibers at a particular wavelength depends upon the Mie scattering pattern for that wavelength. The size of the scattering particles can be determined by analyzing the spectrum of the returned light. In practice, a window in the optical shield on the probe

The **Fulghum** apparatus does not detect spectral artifacts, for example, glare, shadow, blood, mucus, a speculum, or smoke tube. Therefore, one of skill in the art would not be motivated to modify the technique taught in **Fulghum** to practice the invention of any of the claims of the present application.

The Office action alleges that paragraph [0105] of **Fulghum**, reproduced below, discloses an apparatus for determining whether spectral data is affected by an artifact:

[0105] In these experiments the individual spectra are obtained simultaneously with a prism spectrometer which disperses the image of an array of fiber tips (the output ends of the receiving fibers) across a CCD detector array, diagramed schematically 1300 in FIG. 13. The absolute calibration of the spectrometer is not particularly critical, but the relative error between spectra must be minimized to obtain a good difference signal. A steep slope in a common-mode spectrum (like the hemoglobin absorption) combined with a relative wavelength calibration error results in an offset in the difference spectrum. This type of error commonly results from field distortions in the imaging optics of the spectrometer. It has been found that such errors can be reduced by introducing deeply modulated light spectra into the spectrometer and minimizing the resulting squares of the difference spectra with a 2-D polynomial mapping function for

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the spectral error. The modulated light spectrum used was the combined spectra of numerous, evenly-spaced, narrow-band filters placed in the illumination light path. By imaging a vertical array of fibers, through the prism, onto the CCD array all of the spectra can be obtained simultaneously. Binning the spectral channels on the CCD chip returns a 7x255 image containing the seven spectra.

The above passage does not disclose an apparatus for detecting an artifact as recited, for example, in **claim 56** of the present application. Not only does **Fulghum** fail to teach an apparatus for obtaining spectral data using electromagnetic radiation incident at a first angle and subsequently incident at a second angle, as recited in **claim 56**, Fulghum also fails to disclose the use of obtained data to determine whether such data is affected by an artifact, as recited in **claim 56**. Rather, **Fulghum** is interested in avoiding error that "results from field distortions in the imaging optics of the spectrometer" [emphasis added]. This "error" does not result from the presence of an artifact associated with the tissue, such as glare, shadow, blood, mucus, a speculum, and/or smoke tube. Instead, the error described in **Fulghum** is related to the imaging optics.

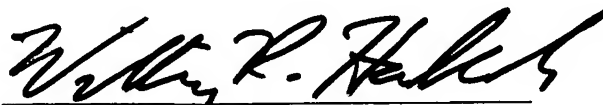
The reference in the above passage to "hemoglobin" does not disclose the detection of blood as an "obstruction", as recited in dependent **claim 61**. It appears that hemoglobin is simply one component of the tissue for which **Fulghum** determines a particle size distribution, and paragraph [0105] above appears to explain why the method is sensitive to problems with the imaging optics of the spectrometer. Hemoglobin is not an "obstruction" in **Fulghum**.

Applicants request that the rejections of independent claims 47, 56, 68, and 69, as well as their dependent claims (which include all other pending claims), be reconsidered and withdrawn, at least for the reasons above, and that the claims be allowed in due course.

### Conclusion

In view of the foregoing, Applicants respectfully request withdrawal of all rejections, and allowance of claims 47-82 in due course. The Examiner is hereby cordially invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues..

Respectfully submitted,



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